Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (Currently amended): A ~~computer implemented~~ method for managing a stability study, the method comprising:

providing one or more first interfaces that enable a user to specify requirements that need to be fulfilled for stability studies;

receiving input via the one or more first interfaces indicative of a set of requirements for the stability study;

providing one or more second interfaces that enable a user to specify actions to be performed for stability studies;

receiving input via the one or more first interfaces indicative of a set of actions to be performed for the stability study;

providing one or more third interfaces that enable a user to specify a set of business rules for stability studies;

receiving input via the one or more third interfaces indicative of a set of business rules for the stability study;

generating one or more fourth interfaces for the stability study based on the set of requirements that need to be fulfilled for the stability study, wherein the one or more fourth interfaces define the set of requirements for the stability study;

displaying the one or more fourth interfaces;

receiving input information [[for]] via the one or more fourth interfaces, the received input information for fulfilling the requirements; and

validating the received input information against the set of business rules for the stability study to determine [[if]] whether the input information is acceptable.

2. (Original): The method of claim 1, further comprising if the input information is acceptable, storing the input information.

3. (Currently amended): The method of claim 1, further comprising:

determining [[if]] whether the set of requirements for the stability study have been completed; and

if the set of requirements have not been completed, outputting [[an]] one or more fifth interfaces [[for]] requesting additional input information for the requirements in the set of requirements that have not been completed.

4. (Currently amended): The method of claim 1, further comprising:

determining [[if]] whether approval from a user is needed for the input information based on the set of actions.

5. (Original): The method of claim 4, further comprising:

receiving an indication of approval from the user; and

storing the indication.

6. (Original): The method of claim 5, wherein the indication comprises at least one of an electronic signature and captured signature.

7. (Currently amended): The method of claim [[5]] 4, further comprising:

receiving an indication from the user of disapproval;

determining requirements that need to be completed for approval; and

outputting [[an]] one or more fifth interfaces ~~needed to complete~~ defining the determined requirements that need to be completed for approval.

8. (Currently amended): The method of claim 1, wherein the one or more fourth interfaces include an interface for a stage in a plurality of stages in the stability study.

9. (Original): The method of claim 8, wherein the plurality of stages comprise at least two of a stability study setup criteria, stability study planning criteria, initial sampling and testing criteria, stability study launch criteria, stability study testing criteria, and stability study evaluation criteria.

10. (Original): The method of claim 1, further comprising outputting information summarizing the stability study.

11. (Original): The method of claim 1, further comprising determining a result of the stability study.

12. (Original): The method of claim 11, wherein the result is inputted by a user.

13.-26. (Canceled).

27. (New): A computer readable medium storing a set of instructions for managing a stability study when executed by a processor of a computer system, the computer readable medium comprising:

code for displaying one or more first interfaces that enable a user to specify requirements that need to be fulfilled for stability studies;

code for receiving input via the one or more first interfaces indicative of a set of requirements for the stability study;

code for displaying one or more second interfaces that enable a user to specify actions to be performed for stability studies;

code for receiving input via the one or more first interfaces indicative of a set of actions to be performed for the stability study;

code for displaying one or more third interfaces that enable a user to specify a set of business rules for stability studies;

code for receiving input via the one or more third interfaces indicative of a set of business rules for the stability study;

code for generating one or more fourth interfaces for the stability study based on the set of requirements that need to be fulfilled for the stability study, wherein the one or more fourth interfaces define the set of requirements for the stability study;

code for displaying the one or more fourth interfaces;

code for receiving input information via the one or more fourth interfaces, the received input information for fulfilling the requirements; and

code for validating the received input information against the set of business rules for the stability study to determine whether the input information is acceptable.

28. (New): The computer readable medium of claim 27, further comprising code for storing the input information when the input information is acceptable.

29. (New): The computer readable medium of claim 27, further comprising:

code for determining whether the set of requirements for the stability study have been completed; and

code for outputting one or more fifth interfaces when the set of requirements have not been completed that request additional input information for the requirements in the set of requirements that have not been completed.

30. (New): The computer readable medium of claim 27, further comprising:

code for determining whether approval from a user is needed for the input information based on the set of actions.

31. (New): The computer readable medium of claim 30, further comprising:

code for receiving an indication of approval from the user; and

code for storing the indication.

32. (New): The computer readable medium of claim 31, wherein the indication comprises at least one of an electronic signature and captured signature.

33. (New): The computer readable medium of claim 30, further comprising:

code for receiving an indication from the user of disapproval;

code for determining requirements that need to be completed for approval; and

code for outputting one or more fifth interfaces defining the determined requirements that need to be completed for approval.

34. (New): A system for managing stability studies, the system comprising:

a first interface configured to enable a user to specify requirements, actions, and business rules for stability studies;

a database configured to store information associated with the requirements, actions, and business rules for stability studies;

a stage selector configured to select a stage of a stability study and to determine from the database one or more requirements for the selected stage;

a stage information manager configured to receive the one or more requirements from the stage selector, to generate a second interface that defines the one or more requirements for the selected stage that need to be fulfilled, and to generate a third interface indicative of information on actions associated with the selected stage that need to be performed;

a stage information processor configured to receive input via the second and third interfaces and to validate the input against business rules associated with the selected stage to determine whether the input is acceptable.

35. (New): The system of claim 34 wherein the first interface is further configured to enable the user to create a specification for a first stability study as an overlay using a specification for a second stability study as a base.